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Effect of Cognitive Behavioral Therapy on Sleep and Opioid Medication Use in Adults with Fibromyalgia and Insomnia

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Summary

Sleep and opioid medications used to treat insomnia and chronic pain are associated with adverse side effects (falls, cognitive disturbance). Although behavioral treatments such as Cognitive Behavioral Therapy for insomnia (CBT-I) and pain (CBT-P) improve sleep and clinical pain, their effects on sleep and opioid medication use are unclear. In this secondary analysis of published trial data we investigated whether CBT-I and CBT-P reduced reliance on sleep/opioid medication in patients with fibromyalgia and insomnia (FMI). Patients with FMI (N=113, M_{age}=53.0, SD=10.9) completed eight weeks of CBT-I (n=39), CBT-P (n=37) or waitlist control (WLC; n=37). Participants completed 14 daily diaries at baseline/post-treatment/6-month follow-up, assessing sleep/opioid medication usage. Multilevel modeling examined group by time effects on days of medication use. A significant interaction revealed CBT-P reduced the number of days of sleep medication use at post-treatment, but usage returned to baseline levels at follow-up. There were no other significant within- or between-group effects. CBT-P led to immediate reductions in sleep medication usage, despite lack of explicit content regarding sleep medication. CBT-I and CBT-P may be ineffective as stand-alone treatments for altering opioid use in FMI. Future work should explore CBT as an adjunct to other behavioral techniques for opioid reduction.

Keywords

hypnotics; opioids; cognitive behavioral therapy; chronic pain; sleep disturbance

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Introduction

Approximately 1 in 5 adults have chronic pain (CDC, 2018), and up to 80% of patients with chronic pain also experience insomnia symptoms (Baker, McBeth, Chew-Graham, & Wilkie, 2017). These data support the bidirectional nature of interaction between chronic pain and disturbed sleep. Pharmacological treatment for chronic pain and chronic insomnia typically involves hypnotics and opioids, respectively (Dowell, Haegerich, & Chou, 2016; Riemann & Perlis, 2009). However, these medications do not consistently provide long-term symptom relief (Peng et al., 2015). Moreover, long-term opioid use is associated with adverse effects, including drug abuse and dependence, overdose, cardiovascular events, and endocrinologic harm (Dowell et al., 2016).

CBT-I and CBT-P show promise in improving both insomnia and chronic pain. Tang and colleagues (2015) systematically reviewed the efficacy of non-pharmacological treatments for chronic insomnia and chronic pain and noted large effect sizes for sleep parameters, during both treatment and follow-up. For example, among individuals with fibromyalgia, CBT-I is associated with 13–18 minute decreases in sleep onset latency and 28–37 minute decreases in wake after sleep onset (Edinger, Wohlgemuth, Krystal, & Rice, 2005). CBT-P is also associated with pain intensity reductions in 50% of patients (Lami et al., 2018). Similarly, in a recent trial, McCrae and colleagues (2019) found that, relative to waitlist control (WLC), 8 weeks of CBT-I or CBT-P reduced insomnia symptoms immediately following treatment. For instance, findings showed reductions in wake time after sleep onset of 30 minutes following CBT-I and 25 minutes following CBT-P, as well sleep efficiency increases of 15% following CBT-I and 7% following CBT-P. Both treatments also prompted clinically significant pain reductions in at least one-third of participants.

Given the impact of CBT-I and CBT-P on both insomnia and clinical pain, these treatments may also have downstream effects on use of hypnotics and opioids to manage insomnia and pain. However, previous findings are mixed. Three studies document no impact of CBT-I on sleep medication use among patients with FMI (Currie, Wilson, Pontefract, & DeLaplante, 2000; Edinger et al., 2005; Martinez et al., 2014). In contrast, Lami and colleagues (2018) found patients receiving combined CBT-I and CBT-P (but not those receiving only CBT-P or usual care) reported significant reductions in frequency of sleep medication use on a single-item, retrospective questionnaire. None of these studies reported pain medication use changes. However, at least one study examining CBT-P's effect on pain medication use among patients with fibromyalgia (without insomnia) reported CBT-related reductions in pain medication use (Falcao et al., 2008).

This study analyzed data from McCrae and colleagues' (2019) randomized controlled trial to examine the impact of CBT-I and CBT-P on hypnotic and opioid medication use among patients with FMI. Because both CBT-I and CBT-P were associated with post-treatment and 6-month reductions in insomnia symptoms in that trial (McCrae et al., 2019), we hypothesized both CBT-I and CBT-P would reduce the frequency of sleep medication use. Relative to WLC, a higher proportion of CBT-P participants reported improved pain at post-treatment and a higher proportion of CBT-I participants reported improved pain at 6-month follow-up; therefore, we hypothesized CBT-P would be associated with reduced opioid use

frequency immediately following treatment and CBT-I would be associated with reduced opioid use frequency at 6-months.

Methods

Participants and Procedure

Participants were recruited as part of a clinical trial investigating the effectiveness of CBT-I and CBT-P in patients with FMI (NCT02001077; McCrae et al., 2019). Participants were randomly assigned to 8-week CBT-I (n=39), CBT-P (n=37), or WLC (*n*=37). Neither treatment included formal or informal components to taper sleep or pain medication. Inclusion criteria were: self-reported pain for 6+ months, tender point confirmation of FM (American College of Rheumatology, 1990 criteria), sleep diary confirmation of insomnia (sleep onset latency [SOL] or wake after sleep onset [WASO] >30 min) on 6+ nights during a 2-week baseline, daytime dysfunction due to insomnia (mood, cognitive, social, or occupational impairment), and no sleep medications for 1+ month or stabilized on sleep medication for 6+ months. See Table 1 for participant demographics. The University of Florida Institutional review board approved all procedures. Written informed consent was provided by each participant.

Interventions

Participants were randomized to CBT-I, CBT-P, or WLC. Intervention details are provided elsewhere (McCrae et al., 2019). Briefly, CBT-I and CBT-P included 8 weekly, 50-minute sessions delivered individually in-person by doctoral clinical psychology students. Therapists were trained/supervised by a licensed clinical psychologist (author CSM). CBT-I included: session 1-sleep education/sleep hygiene, session 2-stimulus control, session 3-relaxation, session 4-sleep restriction, sessions 5–7-cognitive restructuring, and session 8-review/maintenance. CBT-P included: session 1- pain education, session 2-progressive muscle relaxation, session 3-activity-rest cycle, activity pacing, and autogenic relaxation education, session 4-activity-rest cycle problem solving/visual imagery, sessions 5–7-cognitive restructuring, and session 8-review/maintenance. Participants received workbooks outlining treatment techniques/rationales. WLC completed ‘treatment as usual’ and had the choice of completing CBT-I or CBT-P at the end of the study.

Measures

Medication use was assessed using daily sleep diaries, which participants completed for 2 weeks at each assessment. Participants reported standard sleep variables, and if they had used (yes/no) any form of medication, including sleep and opioid medication. Medication names and dosages were recorded. Primary outcomes were yes/no use of sleep medication or opioids.

Data Analysis

Dependent variables included frequency of sleep and opioid medication use. For each outcome, fixed effects of treatment group (CBT-I, CBT-P, WLC) and time (baseline, post-treatment, 6-month follow-up) and the group by time interaction were computed using multilevel modeling in SPSS software. Significant main effects and interactions were

followed by pairwise, Bonferroni-controlled comparisons. Across models, the most parsimonious random structure based on goodness of fit was used. Factors were added to each model's random intercept. Models were evaluated through maximum likelihood estimation.

Results

Table 2 shows the fixed effects of group and time, and their interaction, on sleep medication and opioid use during 14 days at each time point. A significant interaction revealed CBT-P, but not CBT-I or WLC, reduced the average number of days (p=.02; hedge's g = 2.20, a large effect size) of sleep medication usage at post-treatment (M=6.71, SEM=1.1) relative to baseline (M=9.1, SEM=1.0). However, this reduction was not maintained at six-months. There were no significant main or interaction effects for frequency of opioid use.

Discussion

This study examined the effects of CBT-I and CBT-P on sleep and opioid medication use in adults with FMI. Types and level of use of baseline sleep and opioid medication in this sample of patients with fibromyalgia and co-morbid insomnia [sleep medications such as various hypnotics and benzodiazepines, see McCrae et al., 2019; opioid medications such as codeine, oxycodone, etc., see (Curtis et al., 2019)] were relatively consistent with previous research (Edinger et al., 2005; Peng et al., 2015). Overall, 2 out of 5 participants reported using sleep medication and 1 in 3 used pain medication. While use of either type of these medication is not a problem, concurrent use of these and other drugs/medications may increase risk for negative drug interactions and health outcomes (Dowell et al., 2016). Thus, the potential for behavioral interventions to decrease individuals' use of sleep and opioid medication has strong clinical implications.

Relative to baseline, CBT-P (but not CBT-I) led to post-treatment reductions in the number of days (~2) participants used sleep medication; however, this effect was not maintained at follow-up. The significant effect of only one treatment, and only at post-treatment, does not support study hypotheses. Specifically, since both treatments were associated with post-treatment and 6-month reductions in insomnia symptoms (McCrae et al., 2019), we expected both treatments to reduce sleep medication use at both follow-ups. The differential treatment efficacy on sleep medication use may be partially attributable to close monitoring of participants' sleep behaviors in CBT-I. That is, although participants in both treatments were instructed at the beginning of treatment to be consistent with medications (so treatment effects would not be confounded by medication use changes), participants tend to discontinue sleep medications if they feel they no longer need them. However, because monitoring of daily sleep patterns is so integral to CBT-I, CBT-I therapists may have more regularly inquired about sleep medication use, inadvertently keeping CBT-I patients more accountable for consistency with those medications. In contrast, because therapists did not closely monitor/review sleep patterns in CBT-P, CBT-P participants may have felt more freedom to reduce medication use.

Despite post-treatment decline in sleep medication use and maintenance of insomnia symptom improvements, CBT-P participants returned to baseline levels of sleep medication use by 6-month follow-up. Although the sleep medication reduction of large magnitude at post-treatment supports the clinical utility of CBT-P as a potential pathway for reducing reliance on sleep medications in the short-term, findings suggest this is not an effective long-term solution. Similarly, despite clinically significant reductions in pain symptoms in at least one third of participants in both treatments (McCrae et al., 2019), neither had a significant effect on days of opioid use. Given that the majority of participants in the prior trial did not show clinically significant pain reduction, it is likely that overall, pain reduction was not large enough following CBT-I/CBT-P for participants to feel they no longer needed opioid medications. These findings fit with research suggesting strong psychological dependence factors in medication use. Specifically, research suggests it is often difficult for people with insomnia to withdraw from sleep medications without direct intervention (Lichstein et al., 2013). Support also seems integral to reducing opioid use among patients with chronic pain (Sullivan et al., 2017). Based on these findings, it may be important to integrate tailored medication withdrawal protocols into existing treatments if reduction/discontinuation of medication is a treatment goal.

Limitations

This study examined a clinically important outcome of behavioral treatment for insomnia and pain in a population at high risk for negative health outcomes. However, a number of limitations should be noted. Given this study's focus on individuals with fibromyalgia, it is unclear whether these findings generalize to other chronic pain populations. Generalizability is also limited by inclusion of primarily Caucasian, female, and middle-aged to older adult participants. The impact of encouraging participants to maintain consistency in medication use at the start of treatment is also unknown. Future work examining treatment effects on sleep/opioid medication use in persons of color, men, and younger adults is warranted.

Conclusion

Although CBT-I and CBT-P reduce symptoms of both insomnia and clinical pain (McCrae et al., 2019), findings suggest these treatments are not associated with long-term changes in sleep or opioid medication use among patients with FMI. Past studies combining or staggering CBT with medication tapering protocols successfully reduced not only insomnia symptoms and pain severity, but also medication dependency (Cunningham, Evans, King, Gehin, & Loukianova, 2016). Collectively, data support the idea that protocols specific to medication withdrawal may be needed and/or added to current CBT-I and CBT-P protocols to successfully reduce sleep and pain medication use within this population.

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Table 1

Participant characteristics (N=113)

Variable	CBT-I (n=39)	CBT-P (n=37)	WLC (n=37)
Age, years; M (SD)	54.13 (11.03)	51.54 (10.62)	52.27 (11.19)
Female (n; %)	39 (100%)	34 (91.89%)	24 (64.85%)
Ethnicity (n; %)			
White	32 (82.05%)	34 (91.89%)	24 (64.86%)
Black	6 (15.38%)	3 (8.11%)	11 (29.73%)
Native Indian/Alaskan Native	1 (2.56%)	0	1 (2.70%)
Biracial	0	0	1 (2.70%)
Employed (n; %)	17 (43.59%)	12 (32.43%)	13 (35.14%)
Duration of insomnia (months SD)	142.81 (160.52)	140.63 (124.81)	135.77 (139.60)
Duration of Fibromyalgia (months, SD)	114.52 (91.10)	94.74 (76.16)	109.46 (88.62)
Sleep medication (n; %)	13 (33.33%)	17 (45.95%)	17 (29.73%)
Opioid medication (n, %)	10 (25.64%)	17 (45.94%)	9 (24.3%)

Table 2

Descriptive and inferential statistics for sleep medication and opioid use outcomes (N=113).

	Baseline		Post-Treatment		6 months		Group		Time		Grp × Time	
	M	**SE**	**M**	**SE**	**M**	**SE**	**F**	**p**	**F**	**p**	**F**	**p**
Sleep Med Days[a]							0.58	.56	1.24	.29	**3.02**	**.02**
CBT-I	6.90	0.99	7.31	1.14	6.38	1.07						
CBT-P	9.05	1.02	6.71	1.10	8.99	1.05						
WLC	8.43	1.02	8.23	1.12	7.08	1.10						
Opioid Days[a]							2.78	.07	0.65	.52	1.65	.17
CBT-I	1.64	0.82	2.16	0.86	1.61	0.91						
CBT-P	4.68	0.84	3.91	0.85	4.82	0.90						
WLC	3.32	0.84	2.67	0.86	2.93	0.93						

Notes. Med = medication. LRD = lowest recommended dosage. Days of sleep and opioid medication based on 14 days of reporting at each time point.

[a]One way analysis of variance (ANOVA) revealed no baseline group differences in number of days of sleep medications. ANOVA revealed baseline group differences for number of opioid days (p=.041). To examine the influence of these baseline differences on the opioid days analyses, we conducted additional MLM analyses that included baseline values in the model. Results did not change for Group, Time, or Grp × Time interaction terms, indicating that baseline group differences in number of days of opioids do not impact results. Therefore, the values reported values here reflect models that do not include baseline number of opioid days as a covariate.